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PROCEDURES FOR LEAKAGE TESTING AND DISINFECTION OF  
CONTAINMENT BED ISOLATORS AND CONTAINMENT AIRCRAFT  
TRANSIT ISOLATORS (U)

by

A.R. Lejeune

PCN 16B51  
Task No. DPM 18

May 1980

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Procedures are described for leakage testing and decontamination of patient isolators. Techniques are given for use with both the Containment Bed Isolator (CBI) and the Containment Aircraft Transit Isolator (CATI). Some alternative methods for both types of procedures are also suggested.

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I. LEAKAGE TESTING

INTRODUCTION

Portable containment isolators have been provided by Health and Welfare Canada for use by the Surgeon General for transportation and treatment of patients with highly infectious contagious diseases. The design and operation of these units is described in detail elsewhere (1, 2, 3). Containment Bed Isolators (CBI) have been set up ready for use at the National Defence Medical Centre (NDMC) in Ottawa. Containment Aircraft Transit Isolators (CATI) used to transport patients by ground vehicle or military aircraft to bed isolators in treatment centres are also held in readiness at NDMC and CFB Trenton. A number of containment isolators have been purchased and made ready for use at other treatment centres in Canada as well.

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It will be necessary from time to time to establish or check the integrity of all of these patient isolators. A unit exhibiting gross leakage may not provide the safety required for use with patients harboring highly infectious microorganisms. Several systems of testing have been used to identify or demonstrate the presence of leaks in the plastic envelope and auxiliary components (1, 3). Tests using inert gases such as Freon (3) are quite sensitive and make it possible to locate specific points of leakage. The use of biological aerosols (3) is extremely sensitive but is not suited to identifying individual sources of small leaks. Both of these test systems require expensive and complex equipment and sophisticated techniques which would not usually be available in most treatment centres. This report describes a simple pressure test which can be performed with a minimum of special equipment and expert knowledge or training. The results will indicate whether or not there is leakage of sufficient magnitude to warrant more extensive testing or repair.

#### OPERATING PROCEDURES

An initial visual inspection should be made to ensure that all fittings such as gloves, plastic bags, air hoses, etc., are securely fastened and sealed. A visual inspection of seams and joints in the plastic for obvious faults or gaps can also be made at this time. Openings for the ventilation air intakes and exhaust must then be sealed by covering them with plastic bags, rubber gloves or some other airtight material. A tight seal is made with plastic tape or strong elastic bands. An air line is introduced into the plastic envelope through the finger of a glove with an appropriate hole cut from the finger tip. This entry hole is then sealed with tightly applied plastic tape. Compressed air is supplied through this line from a small air pump or compressor to inflate the plastic envelope.

When checking the CBI only, the air supply system provided with the isolator can be used to inflate the envelope. The built-in check valve will seal the exhaust port when the fan is shut off and the

intake port can be sealed by quickly covering the filter intake or end of the separated intake hose with a plastic bag or glove after the envelope is inflated. The CBI may be tested with the supply section attached or the supply section may be tested independently.

If a sufficiently sensitive manometer is available this should be used to measure the pressure differential inside and outside the plastic envelope. A tube to the inside of the envelope may be introduced in the same manner as described for the air pressure line above. An alternative is to use a rubber stopper large enough to fit snugly into a plastic ring on the end of a glove sleeve. Lines for the manometer and compressed air can be inserted through holes bored in the rubber stopper.

Specifications for the test as recommended by the manufacturer are to inflate the isolator to a pressure of 10 mm of water on the gauge and seal off all air lines. If the pressure drops more than 4 mm in 10 minutes a large leak is indicated and this should be located and sealed. If the pressure drop after 10 minutes is less than 4 mm, the pressure is deliberately released to 6 mm and the isolator sealed again and left for one hour. The pressure should not be less than 4 mm after one hour. If the pressure is less than 4 mm, again the leak should be located and sealed. These cycles should be repeated until the pressure drop in the isolator does not change from 6 mm to less than 4 mm in one hour.

In the absence of a suitable manometer, the manufacturer has suggested an alternative technique. Place one of the large plastic bags provided over the supply port in the normal fashion. Inflate the isolator until the bag is fully extended. Leave the isolator for one hour for the temperature and pressure to stabilize. Observe or measure the height of the end of the bag and if this drops more than one inch during the second hour a leak is indicated and should be located and repaired.

If leaks cannot be located and repaired so that the criteria described above can be met, it will be necessary to use the more elaborate

gas leakage test described in Appendix A of STN 451 (3). This will require specialized equipment which must be borrowed or purchased and some training in the operation of this equipment. The use of biological aerosols (3) is not suitable for pinpointing leak locations.

## II. DISINFECTION

### INTRODUCTION

A Containment Bed Isolator (CBI) and a Containment Aircraft Transit Isolator (CATI) contaminated with non-pathogenic test microorganisms have been successfully disinfected with commonly used disinfecting agents (3). Sodium hypochlorite solutions, formaldehyde vapor and liquid solutions and ethylene oxide vapor were all effective without causing any obvious deterioration of the plastics used in construction of the isolators and auxiliary components. When interpreting the results of these tests, it must be borne in mind that the tests were conducted using non-pathogenic T1 coliphage virus and B. subtilis var. niger spores. The effectiveness of these disinfectants on infectious agents such as Ebola or Marburg virus is not known precisely but is assumed to be of the same order as that for T1 coliphage. Also, the procedures described include a large safety factor and would be expected to be adequate to eliminate all known microorganisms.

### OPERATING PROCEDURES

#### Hypochlorite Solutions

The most effective, commonly available disinfectant is a dilute solution of sodium hypochlorite. This can be prepared by using commercial household bleach (Javex or Chlorox) which is a 5.25% solution of sodium hypochlorite. Add one part bleach to 9 parts of distilled water to obtain a 10% solution which will contain the equivalent of 5000 parts per million (ppm) of free available chlorine. Application of this solution to a surface will destroy any microorganisms on that surface in a few minutes.



This solution is corrosive for metals and should be removed by washing or wiping from metal surfaces 15 minutes after application. For materials very susceptible to the action of chlorine, more dilute solutions of bleach (as low as 1% or 500 ppm) may be used provided contact on the surface is maintained for periods of 30 minutes or longer.

Adequate quantities of 10% bleach and sponges or gauze pads for application should always be readily available for immediate use when the isolators are in operation. This solution should be applied immediately to any area or surface where a known or suspected breach of the integrity of the isolator occurs, and before repairs are effected. Periodic use of bleach solutions inside the isolator where contaminated material is likely to make contact is also recommended.

Free available chlorine gradually disappears from hypochlorite solutions exposed to room temperature and light and, in such cases, the solution should be discarded and replaced with a fresh solution after 10 - 14 days of use. Contact of the solution with bare skin is not harmful for one or two minutes provided the area is thoroughly rinsed or washed immediately after. If longer exposure of the hands is anticipated, protective gloves should be worn.

#### Formaldehyde

It will not be possible to get hypochlorite solution into all the crevices and seams of the isolator. For complete disinfection of these areas, and of the air inside the isolator, a vapor disinfectant will be required. Formaldehyde is one of the most effective vapor disinfectants. Formaldehyde vapor can be produced by a fine spray of Formalin (a 37% solution of formaldehyde in water) or by evaporation of solid paraformaldehyde on a hot plate or other heated surface. The paraformaldehyde should be placed in a shallow tray or pan and heated to 200°C. A small fan placed inside the isolator will help to distribute the vapor to all areas of the isolator.

The minimum effective concentration of formaldehyde vapor is 0.3 gm per cubic foot or 10 mgm per liter of air. For the initial ex-

periments (3), the volume of the CATI was estimated at 62 cu ft and the CBI at 390 cu ft. Paraformaldehyde was used with 20 grams being evaporated in the CATI and 129 grams in the CBI. Since evaporation of paraformaldehyde is 90% efficient in producing formaldehyde vapor, the amounts used include an extra 10% required to compensate for this. Formalin contains 40 grams of formaldehyde in 100 cc and the amount required may be calculated as before (i.e., 50 cc for the CATI and 322.5 cc for the CBI).

Formaldehyde vapor is most effective in destroying micro-organisms when the relative humidity is more than 70%. The relative humidity can be raised quickly by spraying a small amount of water into the isolator. Open shallow pans of water or a vaporizer can also be used. Care should be taken not to add excessive amounts of water. Too much will cause condensation droplets of water to form on the plastic and other material inside the isolator. Formaldehyde vapor will dissolve in the droplets and later when the water evaporates will leave deposits of solid paraformaldehyde. These will be very difficult to get rid of since the paraformaldehyde evaporates very slowly at room temperature. Extremely long ventilation periods or a complete wipe-down with wet cloths or sponges will be required to remove the paraformaldehyde deposits. Where the relative humidity is normally high it is recommended that paraformaldehyde be used instead of Formalin as a source of formaldehyde vapor.

The air recirculation system should be shut off during the disinfection period, which should be a minimum of 4 hours and preferably 8 hours. Following this period the air recirculation system can be used to ventilate the isolator to remove the formaldehyde vapor. The air exhaust must be ducted to the outside during this period either directly through a window or through a building vent which exhausts directly to the outside. Ventilation will usually reduce the formaldehyde vapor concentration to safe and undetectable levels in a few hours, but may require several days if heavy deposits of paraformaldehyde are present because of excessive humidity. A safe level is indicated if formaldehyde

cannot be detected by sniffing the exhaust air or air inside the isolator with the ventilation system shut off. A relatively inexpensive gas sampling and measuring device can be obtained from Matheson of Canada, Ltd., the Matheson-Kitagawa Toxic Gas Detector Kit, Model 8014K.

#### Ethylene Oxide

Ethylene oxide is also a very effective disinfectant vapor and offers some advantage over formaldehyde in that it is more penetrating and is effective at relative humidities as low as 30%. One major drawback of ethylene oxide is that the concentration must be at least 10% for best efficiency but it is normally available only as an 18% mixture with carbon dioxide or fluorocarbons in compressed gas containers. To produce a concentration of 10% inside an isolator with this source is very difficult. Pure ethylene oxide is available but mixtures above 3% of pure ethylene oxide in air are highly explosive.

If large autoclaves equipped for gas sterilization are available it may be possible to disinfect the plastic envelope and other components in this manner with ethylene oxide. If the envelope must be collapsed to fit into the autoclave, care should be taken that sufficient openings are provided to allow free penetration of the vapor into the isolator. Personnel performing this operation must be fully protected against infection.

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